



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---------------|----------------------|---------------------|------------------|
| 10/791,219 | 03/02/2004 | Lois Weisman | IOWA:048US | 3887 |
| 7590 | 01/07/2008 | | EXAMINER | |
| Steven L. Highlander Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Avenue AUSTIN, TX 78701 | | | LIU, SAMUEL W | |
| ART UNIT | PAPER NUMBER | | | |
| | 1656 | | | |
| MAIL DATE | DELIVERY MODE | | | |
| 01/07/2008 | PAPER | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|---|------------------------|---------------------|
| Advisory Action Before the Filing of an Appeal Brief | Application No. | Applicant(s) |
| | 10/791,219 | WEISMAN, LOIS |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) The period for reply expires 7 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. The Notice of Appeal was filed on 03 December 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) They raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) They raise the issue of new matter (see NOTE below);
 - (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

- 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
- 5. Applicant's reply has overcome the following rejection(s): _____.
- 6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
- 7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 18.

Claim(s) objected to: claim 19 remains objected to.

Claim(s) rejected: 24-26.

Claim(s) withdrawn from consideration: 33-58 (claims 59-60 are cancelled now).

AFFIDAVIT OR OTHER EVIDENCE

- 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
- 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

- 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
- 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
- 13. Other: See Continuation Sheet.

Continuation of 3. NOTE: Claims 24-26 remain rejected under 35 US 112, second paragraph, because claim 24 is still indefinite in whether or not the minimal length of the oligopeptide is 10 or 15 residues; to which one does the claim refer? .

Continuation of 11. does NOT place the application in condition for allowance because: At pages 7-8, Applicants' response filed 12/3/07 to the Office action mailed 6/1/07 argues against the rejection under 35 USC 112 first paragraph -written description, and submits that the claimed "oligopeptide" (claims 24-26) is useful for producing antibody, also, the response discusses the Prescott reference referring to immunotherapy and asserts that said reference is not related to the antibody production thereof. The response submits that while there are large number of possible "oligopeptides", each of these "oligopeptide" can be easily identified by simply using computer program and then the corresponding sequence identifier can be obtained, and, the sequence can be used to generate the antibody thereof. Thus, the response requests withdrawal of the rejection. The applicants' arguments are found unpersuasive because of the reasons set forth in the rejection in the Office action, and because of the reasons below. The Spec does not describe the species of claimed "genus" ("oligopeptide comprising at least 10 consecutive residues of SEQ ID NO:3") sufficient to represent said genus including any amino acid sequence(s) of the species, nor teaches correlation between structure and function of the claimed "oligopeptide". Use of the peptide to raise an antibody is a common property of any peptides which cannot substitute for the adequate written description of the claimed oligopeptide. The rejection does not discuss the Prescott reference, and thus, the argument based on this reference is not considered herein. The assertion regarding use of computer program to establish the amino acid sequences with the corresponding sequence identifiers for said "oligopeptides" in relative art field does not provide support for adequate description of the structure of the claimed "oligopeptides". Therefore, the Spec fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention. Therefore, the rejection stands.

At pages 8-9, the response argues against the rejection under 35 USC 112, first paragraph, scope enablement, and submits that although the genus of claimed oligopeptides is large, and although not every oligopeptide will produce the antibodies cross-react with the native polypeptide of SEQ ID NO:3 (some of them are non-functional), the skilled artisan can expect that many of said oligopeptides can elicit polyclonal response to produce the antibodies. In addition, the response submits that the Prescott et al. reference deals with allergy vaccines but not the antibody production (page 8, last paragraph). Thus, the response infers that the Spec has provided enablement for claims 24-26, and therefore, requests withdrawal of the rejection.

The applicants' arguments are found unpersuasive because of the reasons set forth in the rejection in the Office action, and because of the reasons below. The claimed genus, i.e., "oligopeptide" is large, as admitted by the applicants' response, encompassing numerous fragments derived from the full-length sequence of SEQ ID NO:3. Thus, the scope of the claims is outside the bound of the enablement. The Prescott et al. teaching suggests unpredictability of using oligopeptides of short peptide fragments as an antigen or vaccine in immuno-therapy. The instant Spec provides no structure, e.g., amino acid sequences of the claimed "oligopeptide" nor teaches the structure-function relationship thereof. In the absence of the Spec teachings and unpredictability of art, screening for and characterizing functional "oligopeptides" consisting of consecutive at least 10 amino acid residues require undue amount and level of experimentation. Therefore, the instant disclosure lack enablement for claims 24-26, and therefore, the rejection is maintained.

At pages 9-10, the response argues that as applicants have amended claims 24-26 to recite a minimum identity (length) of 15 residues, the rejection under 35 USC 102 by Robert et al. should be withdrawn.

The applicants' argument is found unpersuasive because the recitation set forth in the amended claim 24 "an oligopeptide of between 15 and 30 residues, said oligopeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:3" as written is directed to the oligopeptide having the 10 amino acids thereof.

The objection to the Spec is maintained because applicants do not amend the abstract to which is objected. It is noted that the response filed 12/3/07 requests that the objection to the abstract be held abeyance.

Continuation of 13. Other: the objection to claim 18 is withdrawn in light of that claim 18 does not recite "non-Vac14 sequence". Also, the objection to claim 25 is withdrawn in light of that the applicants' argument set forth in the response filed 12/3/07 as to this objection is persuasive.



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER